

## Hemostemix Provides Highlights of 2018 Accomplishments

CALGARY, Alberta, Jan. 17, 2019 -- Hemostemix Inc. (“**Hemostemix**” or the “**Company**”) (TSX VENTURE: HEM; OTCQB: HMTXF) is pleased to provide the following corporate update on accomplishments and milestones that it has achieved in 2018. The past twelve months has seen a transformation in the Company, with a significant amount of progress made on multiple fronts, including patient and site enrollment for the current Phase II clinical trial for critical limb ischemia, manufacturing optimization, research and development, and enhancing its management and scientific team. All of the Company’s efforts in 2018 have furthered the core goal of achieving commercialization of its technology and furtherance of its research and development into new indications for additional clinical trials.

### **Technology Differentiators - Overview**

The key differentiating factor for Hemostemix is that its technology process is based on a simple blood draw from the arm to collect peripheral blood, of which stem cell and progenitor cells are isolated, differentiated and expanded to create a personalized therapy. In contrast, other technologies utilize bone marrow collection which is an invasive and painful procedure, adipose (or fat) tissue which requires liposuction by an experienced physician, or birth tissues which require long-term cryopreservation followed by thawing of the cells which can damage the cell population. In addition, its platform is one that can support numerous indications – such as critical limb ischemia, peripheral arterial disease and heart disease including angina pectoris, using the same product ACP-01. This allows the Company to advance additional indications into phase two trials using the same technology, without having to complete safety or phase one trials.

Hemostemix’s platform technology is based on an autologous (patient’s own) synergetic cell population (“SCP”). SCPs are basically a cell population within the blood consisting of adult stem cells and other supporting cell types. This cell population has the potential to generate various types of cellular products, depending on the culture conditions in which the cells are grown, including angiogenic cell precursors (“ACPs”) which induces blood vessel formation. The Company’s lead product, ACP-01, is for use in treatment of indications with diseased or damaged tissue that require some level of revascularization for patient recovery, including indications driven by peripheral arterial disease (“PAD”) such as critical limb ischemia, as well as heart diseases such as angina pectoris. Diabetes, which is one of the leading causes of PAD, is becoming a worldwide epidemic resulting in significant and increasing healthcare and economic costs. In addition, cardiovascular disease is one of the leading causes of death in the United States and worldwide. Regenerative and stem cell based therapies are at the forefront of modern medicine, garnering significant interest from patients and medical specialists. The Company’s strategy is to focus on these target markets and orphan diseases that have high unmet treatment needs, where its therapies can offer impactful results for patients with few treatment alternatives.

### **Phase II Clinical Trial for CLI - 25% Patient Enrollment Achieved**

The Company currently has a total of 11 clinical trial sites open for patient enrollment and there are nine clinical trial sites in the various stages of the review and start-up process, which the Company anticipates that several of these will be fully greenlighted shortly. Patient enrollment continues to ramp up with recent trial site additions, resulting in a total of 24 patients treated to-date out of the estimated total of 95 required patients to complete the trial. 2018 saw the Company double its number of treated patients reaching 25% enrollment. With the recent on-boarding of new US trial sites, the Company anticipates reaching 50% patient enrollment or 42 patients by spring 2019 and reporting of interim data results would be subject to all of these patients meeting the minimum follow-up protocols.

The Company specifically targets strategic clinical sites throughout the United States and Canada that are known for their ability to accelerate patient enrollment and complete clinical trials. The Company has been successful in attracting principal investigators at these sites that are all top of their field heart and/or vascular surgeons or other specialists. The Company continues to see positive interest in its trial and the need for new treatments for CLI that could offer an alternative to life altering amputations which is currently one of the limited treatment options available for some people suffering from CLI.

### **Future Clinical Trials and Additional Indications**

As previously announced, the Company has been working on a pre-IND submission for the FDA for a Phase II or potentially a Phase III clinical trial for angina pectoris and intends to file this submission with the FDA in Q1 2019. The Company has collected substantial data on ACP-01 over the years, and believes the safety and efficacy profiles will facilitate submissions to the FDA and Health Canada for additional indications. Future indications that the Company intends to explore include Idiopathic Pulmonary Hypertension (“IPH”) which is another orphan disease, and men’s health issues related to diabetes such as erectile dysfunction.

### **Commercialization Strategy**

As noted above, the Company is currently focusing on commercialization of a treatment therapy for CLI with ACP-01 within its current clinical trial and is also preparing a submission for the use of ACP-01 in a heart trial, such as angina pectoris. Another product initiative will be the development of NCP-01, our neural cellular precursor (“NCP”) product.

As announced in February 2018, Hemostemix entered into a licensing agreement with its contract manufacturing partner

Aspire Health Science, LLC (“Aspire”), which gave Aspire exclusive rights to use and sell ACP-01 in the Bahamas, Costa Rica, the Dominican Republic, Mexico, Panama, and the State of Florida for use in approved open trials and compassionate care cases. Aspire has been working with the Bahamas Ministry of Health and Dr. Conville Brown in Nassau, Bahamas, to start an open trial for congestive heart failure (CHF) involving 20 patients and an open trial for 20 patients for CLI. Pursuant to its licensing agreement, all of the data collected by Aspire pursuant to these proposed trials would belong to Hemostemix.

The Company continues to pursue sources of funding, including potential grants and partnering or other licensing transactions.

### **Research and Development Yields Results**

2018 saw several research breakthroughs that enhanced its manufacturing and product offerings and supported the Company’s commercialization efforts. The Company performed testing on over 40 research batches during 2018. This resulted in the further expansion of the ACP-01 technology process to also support an allogeneic process which involves the use of donor or third-party blood that can be processed and then used to treat a patient. Patients who are too ill or suffer comorbidities (having multiple diseases) may provide a poor blood sample for autologous processing, ultimately leaving these patients without stem cell treatment options. Being able to use healthy donor blood would allow for the potential ability to treat all patients, including those who are very ill, for whom an autologous treatment is not optimal.

In addition, internal research also proved that product manufacturing time can be reduced by 40% to 3 days from 5 days. Upon approval by regulatory authorities for use, the shortened manufacturing process should not only reduce future costs for all of ACP-01 applications, but also result in an approximate 67% increase in the amount of product treatments that can be manufactured under its existing manufacturing contract. The Company intends to apply for regulatory approval in order to utilize this optimized process in its current Phase II clinical trial for CLI. Looking to the future, the Company intends to build on its manufacturing achievements to-date and conduct further R&D work to partially, if not fully, automate the manufacturing process which it feels is a significant factor for global commercialization.

The Company also recently initiated an R&D program for generation of NCP-01 (Neural Cellular Precursors) from peripheral blood. The Company’s R&D will focus on showing that NCP-01 is a product candidate that has the potential to treat such indications as amyotrophic lateral sclerosis (“ALS”), spinal cord injuries, Parkinson’s disease and Alzheimer’s disease through building new neuronal lineage cells in a patient. The Company believes, these are important markets with significant unmet medical treatment needs.

### **Increasing US and Global Exposure**

In order to increase the Company’s exposure in the United States and worldwide, the Company has focused on several key strategies. Firstly, in October 2018, the Company was approved for up-listing its common shares for trading on the OTCQB Venture Market, a US trading platform that is operated by the OTC Markets Group in New York. The Company also secured DTC and CNS eligibility by The Depository Trust Company (“DTC”) for electronic settlement and transfer of its common shares in the United States. A US listing will provide exposure to a broader audience, which complements the Company’s focus on adding key clinical trial sites throughout the United States.

Hemostemix has also recently attended key investment conferences and summits, including the 7th Global Family Office Investment Summit sponsored by the Ritossa Family Office held in Dubai, United Arab Emirates, the Mid Small Cap Forum sponsored by Lond Capital held in San Francisco, California as well as the 2019 JP Morgan Healthcare Conference held in San Francisco, California. All of these events included a focus on biotech investments with numerous institutions and other impact investors in attendance. The Company plans to attend the upcoming World Stem Cell Summit in Miami and the BIO CEO & Investor Conference in New York City which is one of the largest investor conferences focused on established and emerging publicly traded and select private biotech companies. The Company continues to focus on attracting new retail and institutional investors to its shareholder base.

### **Intellectual Property**

The Company recognizes protecting and expanding its intellectual property portfolio is of key importance. The Company has a broad and growing patent portfolio which covers 5 patent families with over 50 patents issued and pending in several important jurisdictions, including the United States, Canada, Europe, Japan and China. Earlier this year, the EU Patent and Trademark Office granted patent number EP1833962 “Regulating Stem Cells”, which is part of a family of patents the Company has in its extensive patent portfolio. This patent has previously been granted in Canada and the United States and covers a method for generating therapeutic precursor cell products, including the Company’s lead product ACP-01. Having this patent awarded in the EU is significant as it provides validation in multiple countries and provides the platform to be able to expand clinical trials, commercialization and partnering efforts throughout Europe.

### **Medical and Scientific Team Additions**

Building on the executive management changes in 2017 and 2018, the Company also added key scientific and medical personnel in 2018 including the addition of Dr. Alan Jacobs, M.S.EE, M.D, Ph.D., as chief medical consultant and Ms. Catherine St. George, CCRP, as clinical trial manager.

Dr. Jacobs brings over 20 years of experience developing, manufacturing and launching commercial products and FDA approved therapeutics while Ms. St. George has over 20 years of clinical research experience in phase II and III drug and device trials and has played a key management role for numerous multi-site clinical trials across the United States and Canada spanning multiple therapeutic disciplines.

2018 also saw the formal launch of the Company's Scientific Advisory Board, whose members are all leaders in their fields of expertise, which span biochemistry, molecular biology, genomics and medicine. Members of the SAB are: Dr. Alan B. Lumsden, M.D., who is the Walter W. Fondren III Chair, Medical Director of the Houston Methodist DeBakey Heart & Vascular Center and chair of the Department of Cardiovascular Surgery at Houston Methodist Hospital; Dr. Norman C. W. Wong, B.Sc (Hon), M.Sc, M.D., FRCP(C), Co-Founder and Chief Scientific Officer of Resverlogix Corp. (TSX:RVX), and Dr. Kumar Hari, PhD, whose expertise spans chromosome biology, functional genomics, and bioinformatics.

"As a team, we have reached several significant milestones in the past twelve months which has created real value for the Company and shareholders" commented Kyle Makofka, President and CEO of Hemostemix. "We remain focused on our mission of advancing our technology, executing on our business objectives and moving forward to commercialization. In 2018 our focus was on laying a solid foundation for growth, which we successfully accomplished on several fronts, including the current clinical trial, research and development initiatives, enhancing our executive and management team and manufacturing optimization. Obtaining FDA approval for the CLI trial in 2018 led to ten US trial sites being fully on-boarded with patient treatment doubling as a result. 2019 will be an exciting year for the Company as we focus on several transformative events including reaching the CLI trial interim data point which will validate our technology, making submissions to the US FDA for additional indications including angina pectoris and continuing to develop new impactful therapies for the future through our technology platform. We would like thank our investors for their continued support of the Company as we continue to build on our achievements and transform the Company, making the Company one to watch in 2019."

## **ABOUT HEMOSTEMIX INC.**

Hemostemix is a publicly traded clinical-stage biotechnology company that develops and commercializes innovative blood-derived cell therapies for medical conditions not adequately addressed by current treatments. It is one of the first clinical-stage biotech companies to test a stem-cell therapy in an international, multicenter, Phase II clinical trial for patients with critical limb ischemia ("CLI"), a severe form of peripheral artery disease ("PAD") caused by reduced blood flow to the legs. The Phase II trial targets a participant's diseased tissue with proprietary cells grown from his or her blood that can support the formation of new blood vessels. The Company's intellectual property portfolio includes over 50 patents issued or pending throughout the world. Hemostemix has a manufacturing contract with Aspire Health Science, LLP ("Aspire"), for the production of ACP-01 and for research and development purposes at Aspire's Orlando, Florida, facility. Building towards commercialization, Hemostemix has also licensed the use, sale and import of ACP-01 for certain indications to Aspire in certain jurisdictions. The Company is continuing research and development of its lead product, ACP-01 with other applications, including cardiovascular, neurological and vascular indications.

For more information, please visit [www.hemostemix.com](http://www.hemostemix.com) or email [office@hemostemix.com](mailto:office@hemostemix.com).

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